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Sepracor Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: ESZOPICLONE PATENT LITIGATION

SEPRACOR INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., WOCKHARDT USA, INC., WOCKHARDT LTD., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., ROXANE LABORATORIES, INC., COBALT LABORATORIES INC., COBALT PHARMACEUTICALS INC., GLENMARK GENERICS INC., USA, GLENMARK GENERICS, LTD., GLENMARK PHARMACEUTICALS, LTD., ORCHID CHEMICALS & PHARMACEUTICALS, LTD., ORCHID HEALTHCARE (a Division of ORCHID CHEMICALS & PHARMACEUTICALS LTD.), ORGENUS PHARMA INC., LUPIN PHARMACEUTICALS, INC., LUPIN LTD., SUN PHARMA GLOBAL INC., SUN PHARMACEUTICAL INDUSTRIES INC., SUN PHARMACEUTICAL INDUSTRIES LIMITED, ALPHAPHARM PTY. LTD., MYLAN, INC.,

Defendants.

Civil Action No. 09-1302 (DMC) (MF)

CONSENT JUDGMENT AND ORDER OF PERMANENT INJUNCTION

This action for patent infringement (the "Litigation") has been brought by Plaintiff Sepracor Inc. ("Sepracor") against Wockhardt Ltd. and Wockhardt USA LLC (collectively, "Wockhardt") for infringement of United States Patent Nos. 6,444,273, 6,319,926, 6,864,257, and 7,381,724 (collectively, the "Sepracor Patents"). Sepracor's commencement of the Litigation was based on its receipt of notice from Wockhardt that Wockhardt had filed ANDA No. 91-165 with the United States Food and Drug Administration containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) directed to the Sepracor Patents and seeking approval to market generic versions of 1, 2, and 3 mg tablets of eszopiclone.

Sepracor and Wockhardt have agreed to enter into a good faith final settlement agreement regarding this Litigation on the expectation and belief that this would eliminate the substantial litigation costs that would otherwise be incurred by both Sepracor and Wockhardt during the Litigation, while also serving the public interest by saving judicial resources and avoiding the risks to each of the parties associated with infringement. This reasonable final settlement will afford Sepracor and Wockhardt the procompetitive opportunity to more productively use money and other resources that would have been spent in the continued prosecution and defense of this Litigation, to the benefit of the parties and consumers alike, such as by investing more money in pharmaceutical research and development.

Each of Sepracor and Wockhardt acknowledge there is significant risk to each of them associated with the continued prosecution of this Litigation and have consented to judgment through a final settlement as reflected in the consent judgment set forth herein. The Court, upon the consent and request of Sepracor and Wockhardt, hereby acknowledges the following Consent Judgment and, upon due consideration, issues the following Order.

Sepracor and Wockhardt now consent to this Consent Judgment and Order of Permanent Injunction and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

1. This Court has subject matter jurisdiction over this patent infringement action and personal jurisdiction over Sepracor and Wockhardt for purposes of this action only. Venue is proper in this Court as to Sepracor and Wockhardt as to this action only.

2. In this Litigation, Sepracor has charged Wockhardt with infringement of the Sepracor Patents in connection with Wockhardt's submission of Abbreviated New Drug Application ("ANDA") No. 91-165 directed to generic tablets containing 1, 2, and 3 milligrams of eszopiclone per tablet ("Wockhardt's ANDA No. 91-165 Products") to the U.S. Food and Drug Administration ("FDA").

3. In response to Sepracor's charges of patent infringement, Wockhardt has alleged certain defenses and counterclaims, including that the Sepracor Patents are invalid, unenforceable and/or not infringed. No decision has been obtained by the parties from this Court regarding these charges of infringement or these defenses and counterclaims.

4. Wockhardt has not obtained a decision from the Court finding that it has rebutted the statutory presumption that the Sepracor Patents are valid and enforceable in the Litigation. This admission is without prejudice to Wockhardt's defenses and counterclaims that the Sepracor Patents are invalid.

5. Wockhardt admits that the submission of ANDA No. 91-165 containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of Wockhardt's ANDA No. 91-165 Products within the United States before the expiration of

the Sepracor Patents was a technical act of infringement of the Sepracor Patents under 35 U.S.C. § 271 (e)(2)(A). This admission is without prejudice to Wockhardt's defenses and counterclaims. This admission is further without prejudice to any claim, defense or counterclaim in any future action between Wockhardt and Sepracor, or any successor-in-interest to Sepracor, regarding the Sepracor Patents and/or a generic eszopiclone product other than Wockhardt's ANDA No. 91-165 Products.

6. Both parties have agreed that each of the defenses and counterclaims set forth in Wockhardt's Answer, Affirmative Defenses and Counterclaims, as amended, including the allegations and averments contained therein, should be dismissed, without prejudice.

7. Wockhardt, their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any generic tablet product containing 1, 2, and/or 3 milligrams of eszopiclone per tablet that is the subject of ANDA No. 91-165 until:

(a) The expiration date of U.S. Patent 6,444,673 ("the '673 patent") including a patent term extension pursuant to 35 U.S.C. § 156, minus two and one half months (i.e., November 30, 2013);

(b) in the event that prior to November 30, 2013, the FDA grants pediatric exclusivity for Lunesta®, the expiration date of the '673 patent, including a patent term extension pursuant to 35 U.S.C. § 156, and extended by six months by pediatric exclusivity pursuant to 21 U.S.C. § 355a, minus two and one half months (i.e., May 31, 2014); or

(c) at such earlier date as may be permitted by the Settlement and License Agreement that the Parties have entered into.

8. Sepracor and Wockhardt each expressly waives any right to appeal or otherwise move for relief from this Consent Judgment And Order of Permanent Injunction.

9. This court retains jurisdiction over Sepracor and Wockhardt for purposes of enforcing this Consent Judgment And Order of Permanent Injunction.

10. This Consent Judgment and Order of Permanent Injunction is without prejudice to, and shall have no preclusive effect as to, any claim, defense or counterclaim in any future action between Wockhardt, or any successor-in-interest to Wockhardt, and Sepracor, or any successor-in-interest to Sepracor, regarding the Sepracor Patents and/or a generic eszopiclone product other than Wockhardt's ANDA No. 91-165 Products. Further, this Consent Judgment and Order of Permanent Injunction shall not be admissible in evidence, as an admission of Wockhardt or otherwise, in any such future action.

11. The Clerk of the Court is directed to enter this Consent Judgment And Order of Permanent Injunction forthwith.

IT IS SO STIPULATED:

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SO ORDERED:

This 19 day of August, 2010

HONORABLE DENNIS M. CAVANAUGH
UNITED STATES DISTRICT JUDGE